Article - Health - General

[Previous][Next]

§21–2B–01.

(a) In this subtitle the following words have the meanings indicated.

(b) "Carrier" has the meaning stated in § 15–10A–01(c) of the Insurance Article.

(c) "Eligible patient" means an individual who:

(1) Has a terminal illness, attested to by the individual's treating physician;

(2) Has considered all other treatment options currently approved by the United States Food and Drug Administration;

(3) Has received a recommendation from the individual's treating physician for the use of an investigational drug, biological product, or device;

(4) (i) Has given informed consent for the use of the investigational drug, biological product, or device; or

(ii) If the individual is a minor or lacks the mental capacity to provide informed consent, has a parent or legal guardian who has given informed consent on the individual's behalf for the use of the investigational drug, biological product, or device;

(5) Is ineligible for or unable to participate in a clinical trial; and

(6) Has documentation from the individual's treating physician that the individual meets the requirements of items (1) through (5) of this subsection.

(d) "Health occupations board" means a board established under the Health Occupations Article that issues licenses to practice a health occupation in the State.

(e) "Informed consent" means a written document prepared using the informed consent form developed by the Office of the Attorney General in accordance with § 21–2B–02(d)(1) of this subtitle that:

(1) Is signed by the patient or a parent or legal guardian of the patient;

(2) Is attested to by the patient's treating physician and a witness; and

(3) At a minimum:

(i) Explains the currently approved products and treatments for the disease or condition from which the patient suffers;

(ii) Attests to the fact that the patient concurs with the patient's treating physician in believing that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life;

(iii) Identifies clearly the specific proposed investigational drug, biological product, or device that the patient is seeking to use;

(iv) Informs the provider and eligible patient of any known or anticipated side effects, risks, or reported patient discomfort that is likely related to the treatment;

(v) Describes the best and worst potential outcomes of using the investigational drug, biological product, or device with a realistic description of the most likely outcome, including the possibility that new, unanticipated, different, or worse symptoms might result and that death could be hastened by the proposed treatment, based on the treating physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition;

(vi) Makes clear that the patient's carrier and health care provider are not obligated to pay for any care or treatments that are necessary as a result of the use of the investigational drug, biological product, or device except as required by federal or State law or contract;

(vii) Makes clear that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment with the investigational drug, biological product, or device and that hospice care may be reinstated if this treatment ends and the patient meets hospice eligibility requirements; and

(viii) States that the patient understands that the patient may be liable for all expenses relating to the use of the investigational drug, biological product, or device and that this liability extends to the patient's estate, but not the heirs or legatees of the patient.

(f) "Investigational drug, biological product, or device" means a drug, biological product, or device that:

(1) Has successfully completed Phase I of a clinical trial but has not yet been approved for general use by the United States Food and Drug Administration; and

(2) Remains under investigation or in a clinical trial approved by the United States Food and Drug Administration.

(g) "Terminal illness" means a disease or condition that, without life–sustaining procedures, will result in death or a state of permanent unconsciousness from which recovery is unlikely within 12 months.

[Previous][Next]